

Form PTO 1449 US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO: P-PM 3474	SERIAL NO.: 09/288,344
	APPLICANT: Seidman and Théorêt	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: 4/8/99	GROUP: Art Unit 1623

U. S. PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE

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EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)

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**	AR	Aarbakke et al., "Thiopurine biology and pharmacology, Second Thiopurine Symposium, 19-20 (1996).
<i>Re</i>	AS!	Andersen et al., "Pharmacokinetics, dose adjustments, and 6-mercaptopurine/methotrexate drug interactions in two patients with thiopurine methyltransferase deficiency," <u>Acta Paediatr.</u> , 87:108-111 (1998).
<i>Re</i>	AT	Balis et al., "Pharmacokinetics and Pharmacodynamics of Oral Methotrexate and Mercaptopurine in Children With Lower Risk Acute Lymphoblastic Leukemia: A Joint Children's Cancer Group and Pediatric Oncology Branch Study," <u>Blood</u> , 92(10):3569-3577 (1998). (11/15/98)
<i>Re</i>	AU!	Bergan et al., "Patterns of Azathioprine Metabolites in Neutrophils, Lymphocytes, Reticulocytes, and Erythrocytes: Relevance to Toxicity and Monitoring in Recipients of Renal Allografts," <u>Ther. Drug Monit.</u> , 19:502-509 (1997).

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** See PTO-892 for complete citation.

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<i>Re</i>	AV!	Bergan et al., "Monitored High-Dose Azathioprine Treatment Reduces Acute Rejection Episodes After Renal Transplantation," <u>Transplantation</u> , 66(3):334-339 (1998). (08/15/98)
<i>Re</i>	AW	Black et al., "Thiopurine Methyltransferase Genotype Predicts Therapy-Limiting Severe Toxicity from Azathioprine," <u>Annals of Internal Medicine</u> , 129(9):716-718 (1998). (11/01/98).
<i>Re</i>	AX!	Bökkerink et al., "6-Mercaptopurine: Cytotoxicity and Biochemical Pharmacology in Human Malignant T-Lymphoblasts," <u>Biochem. Pharm.</u> , 45(7):1455-1463 (1996).
<i>Re</i>	AY!	Bostrom and Erdmann, "Cellular Pharmacology of 6-Mercaptopurine in Acute Lymphoblastic Leukemia," <u>The American Journal of Pediatric Hematology/Oncology</u> , 15(1):80-86 (1993).
<i>Re</i>	AZ!	Cattan et al., "6-Mercaptopurine pharmacokinetics and blood lymphocyte subpopulations in patients with Crohn's disease treated with azathioprine," <u>Gastroenterol. Clin. Biol.</u> , 22:160-167 (1998).
<i>Re</i>	BR!	Chan et al., "Azathioprine Metabolism: Pharmacokinetics of 6-Mercaptopurine, 6-Thiouric Acid and 6-Thioguanine Nucleotides in Renal Transplant Patients," <u>J. Clin. Pharmacol.</u> , 30:358-363 (1990).
<i>Re</i>	BS!	Chrzanowska and Krzymanski, "Determination of 6-Thioguanine and 6-Methylmercaptopurine Metabolites in Renal Transplantation Recipients and Patients With Glomerulonephritis Treated With Azathioprine," <u>Ther. Drug Monit.</u> , 21:231-237 (1999).
<i>Re</i>	BT	Colonna and Korelitz, "The Role of Leukopenia in the 6-Mercaptopurine-Induced Remission of Refractory Crohn's Disease," <u>Amer. J. Of Gastroenterology</u> , 89:362-366 (1994). (March, 1994).

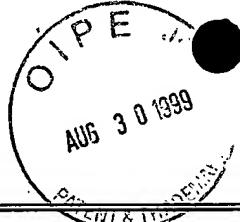
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<i>Me</i>	BV!	Cuffari et al., "6-Mercaptopurine metabolism in Crohn's disease: correlation with efficacy and toxicity," <u>Gut</u> , 39:401-406 (1996).
<i>Me</i>	BW!	Cuffari et al., "Quantitation of 6-thioguanine in peripheral blood leukocyte DNA in Crohn's disease patients on maintenance 6-mercaptopurine therapy," <u>Can. J. Physiol. Pharmacol.</u> , 74:580-585 (1996).
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<i>Me</i>	BY!	Dervieux and Boulieu, "Simultaneous determination of 6-thioguanine and methyl 6-mercaptopurine nucleotides of azathioprine in red blood cells by HPLC," <u>Clin. Chem.</u> , 44(3):551-555 (1998).
<i>Me</i>	BZ	Dubinsky et al., "6-MP Metabolite Levels Predict Clinical Efficacy and Drug Toxicity in Pediatric IBD," <u>J. Pediatr. Gastro. Nutr.</u> , 27:465 (1998). (October, 1998).
<i>Me</i>	CR	El-Gamel et al., "Effect of Allopurinol on the Metabolism of Azathioprine in Heart Transplant Patients," <u>Transplantation Proceedings</u> , 30:1127-1129 (1998).
<i>Me</i>	CS!	Erb et al., "Pharmacokinetics and metabolism of thiopurines in children with acute lymphoblastic leukemia receiving 6-thioguanine versus 6-mercaptopurine," <u>Cancer Chemother. Pharmacol.</u> , 42:266-272 (1998).

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<i>Me</i>	CU!	Giverhaug et al., "Increased Concentrations of Methylated 6-Mercaptopurine Metabolites and 6-Thioguanine Nucleotides in Human Leukemic Cells <i>In Vitro</i> by Methotrexate," <i>Biochem. Pharmacol.</i> , 55:1641-1646 (1998). (Issue No. 10).
<i>Me</i>	CV!	Jacqz-Aigrain et al., "Thiopurine methyltransferase activity in a French population: h.p.l.c. assay conditions and effects of drugs and inhibitors," <i>Br. J. Clin. Pharmac.</i> , 38:1-8 (1994).
<i>Me</i>	CW!	Keuzenkamp-Jansen et al., "Thiopurine methyltransferase: a review and a clinical pilot study," <i>J. Chromatog. B</i> , 678:15-22 (1996).
<i>Me</i>	CX!	Kirschner, "Safety of Azathioprine and 6-Mercaptopurine in Pediatric Patients With Inflammatory Bowel Disease," <i>Gastroenterology</i> , 115:813-821 (1998). (Issue No. 4)
<i>Me</i>	CY!	Klemetsdal et al., "Identification of factors regulating thiopurine methyltransferase activity in a Norwegian population," <i>Eur. J. Clin. Pharmacol.</i> , 44:147-152 (1993).
<i>Me</i>	CZ!	Kröplin et al., "Determination of Thiopurine Methyltransferase Activity In Erythrocytes Using 6-Thioguanine as the Substrate," in <i>Purine and Pyrimidine Metabolism in Man IX</i> , Griesmacher et al., Eds., 142:741-745 (1998). (Plenum Press, New York, NY).
<i>Me</i>	DR!	Krynetski and Evans, "Cancer Genetics '98, Pharmacogenetics of Cancer Therapy: Getting Personal," <i>Am. J. Hum. Genet.</i> , 63:11-16 (1998).

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<i>me</i>	DT!	Lennard et al., "Childhood Leukaemia: A Relationship Between Intracellular 6-Mercaptopurine Metabolites and Neutropenia," <u>Br. J. Clin. Pharmac.</u> 16:359-363 (1983).
<i>me</i>	DU!	Lennard et al., "Thiopurine pharmacogenetics in leukemia: Correlation of erythrocyte thiopurine methyltransferase activity and 6-thioguanine nucleotide concentrations," <u>Clin. Pharm. Ther.</u> , 41(1):18-25 (1987).
<i>me</i>	DV	Lennard et al., "Genetic variation in response to 6-mercaptopurine for childhood acute lymphoblastic leukaemia," <u>Lancet</u> , 336:225-229 (1990) (7/28/90)
<i>me</i>	DW!	Lennard L., "The clinical pharmacology of 6-mercaptopurine," <u>Eur. J. Clin. Pharmacol.</u> , 43:329-339 (1992).
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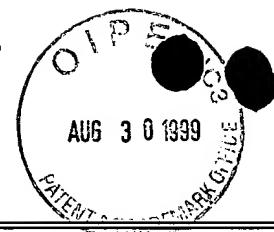
<i>src</i>	ER!	Lennard et al., "Intracellular metabolites of mercaptopurine in children with lymphoblastic leukaemia: a possible indicator of non-compliance?" <u>Br. J. Cancer</u> , 72(4):1004-1006 (1995).
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<i>re</i>	ET!	Lennard L., "Clinical Implications of Thiopurine Methyltransferase-Optimization of Drug Dosage and Potential Drug Interactions," <u>Ther. Drug Monit.</u> , 20:527-531 (1998). (Issue No. 5).
<i>re</i>	EU!	Lilleyman and Lennard, "Mercaptopurine metabolism and risk of relapse in childhood lymphoblastic leukaemia," <u>Lancet</u> , 343:1188-1190 (1994). (5/14/94)
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<i>re</i>	EW	McLeod et al., "Polymorphic Thiopurine Methyltransferase in Erythrocytes Is Indicative of Activity in Leukemic Blasts From Children With Acute Lymphoblastic Leukemia," <u>Blood</u> , 85(7):1897-1902 (1995). (04/10/95).
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<i>re</i>	EY	Present et al., "6-Mercaptopurine in the Management of Inflammatory Bowel Disease: Short- and Long-Term Toxicity," <u>Annals of Internal Medicine</u> , 111:641-649 (1989). (10/15/89).
<i>re</i>	EZ	Relling et al., "Prognostic Importance of 6-Mercaptopurine Dose Intensity in Acute Lymphoblastic Leukemia," <u>Blood</u> , 93(9):2817-2823 (1999). (05/01/99).

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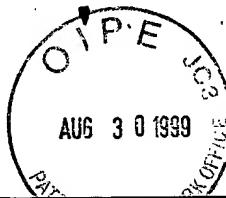
<i>Re</i>	FR	Sandborn and Tremaine, "Measurement of Thiopurine Methyltransferase (TMPT) Activity In Patients With Inflammatory Bowel Disease (IBD) Does Not Predict Side Effects From Treatment With 6-Mercaptopurine (6-MP) Or Azathioprine," <u>Gastroenterology</u> , 104(4):A774 (1993). (April, 1993).
<i>Re</i>	FS	Sandborn et al., "An Intravenous Loading Dose of Azathioprine Decreases the Time to Response in Patients With Crohn's Disease," <u>Gastroenterology</u> , 109:1808-1817 (1995). (December, 1995).
<i>Re</i>	FT	Sandborn, "A Review of Immune Modifier Therapy for Inflammatory Bowel Disease: Azathioprine, 6-Mercaptopurine, Cyclosporine, and Methotrexate," <u>Amer. J. Of Gastroenterology</u> , 91(3):423-433 (1996). (March, 1996).
<i>Re</i>	FU	Sandborn, "6-MP Metabolite Levels: A Potential Guide to Crohn's Disease Therapy," <u>Gastroenterology</u> , 113(2):690-692 (1997).
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<i>Re</i>	FX	Schmiegelow et al., "Risk of Relapse in Childhood Acute Lymphoblastic Leukemia Is Related to RBC Methotrexate and Mercaptopurine Metabolites During Maintenance Chemotherapy," <u>J. Clin. Oncol.</u> , 13(2):345-351 (1995). (02/95).
<i>Re</i>	FY	Snow et al., "The Role of Genetic Variation in Thiopurine Methyltransferase Activity and the Efficacy and/or Side Effects of Azathioprine Therapy in Dermatologic Patients," <u>Arch. Dermatol.</u> , 131:193-197 (1995). (February, 1995).

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<i>Re</i>	FZ!	Vogt et al., "The importance of methylthio-IMP for methylmercaptopurine ribonucleoside (Me-MPR) cytotoxicity in Molt F4 human malignant T-lymphoblasts," <u>Biochimica et Biophysica Acta</u> , 1181:189-194 (1993).
<i>Re</i>	GR	Warren et al., "Quantitation of 6-Thioguanine Residues in Peripheral Blood Leukocyte DNA Obtained from Patients Receiving 6-Mercaptapurine-based Maintenance Therapy," <u>Cancer Res.</u> , 55:1670-1674 (1995). (04/14/95).
<i>Re</i>	GS!	Welch et al., "Pharmacokinetics of Mercaptopurine: Plasma Drug and Red Cell Metabolite Concentrations After an Oral Dose," <u>Ther. Drug Monit.</u> , 19:382-385 (1997).
<i>Re</i>	GT!	Zins et al., "Simultaneous Determination of Azathioprine and Its Metabolites in Plasma Using a High Pressure Liquid Chromatography Assay," <u>Gastroenterology</u> , 110(4):A1054 (1996).
<i>Re</i>	GU!	Zins et al., "A Dose Ranging Study of Azathioprine Pharmacokinetics Following Single Dose Administration of a Delayed Release Oral Azathioprine Formulation," <u>Gastroenterology</u> , 110(4):A1054 (1996).
<i>Re</i>	GV!	Zins et al., "A Dose-Ranging Study of Azathioprine Pharmacokinetics After Single-Dose Administration of a Delayed-Release Oral Formulation," <u>J. Clin. Pharmacol.</u> , 37:38-46 (1997).

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<i>Me</i>	GY!	Goldstein et al., "Toxicities and infections associated with chronic 6-mercaptopurine (6-MP) use in Crohn's disease (CD): Do we need to discontinue treatment?" <u>Gastroenterology</u> , 114:AXXX (1998). Abst. A4041.
<i>Me</i>	GZ	Hawthorne et al., "Randomized controlled trial of azathioprine withdrawal in ulcerative colitis," <u>Br. Med. J.</u> , 305:20-22 (1992). (07/04/92).

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<i>JLc</i>	HS	Lennard et al., "Pharmacogenetics of acute azathioprine toxicity: relationship to thiopurine methyltransferase genetic polymorphism," <u>Clin. Pharmacol. Ther.</u> , 46:149-154 (1989). (August, 1989).
<i>JLc</i>	HT	Markowitz et al., "Long-term 6-mercaptopurine treatment in adolescents with Crohn's disease," <u>Gastroenterol.</u> , 99:1347-1351 (1990). (November, 1990).
<i>JLc</i>	HU	Markowitz et al., "Immunosuppressive therapy in pediatric inflammatory bowel disease: results of a survey of the North American Society for Pediatric Gastroenterology and Nutrition. Subcommittee on immunosuppressive use of the Pediatric IBD Collaborative Research Forum, <u>Am. J. Gastroenterol.</u> , 88:44-48 (1993). (January, 1993).
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<i>JLc</i>	HW!	Markowitz et al., "Relationship of leukopenia to 6-MP induced remission of Crohn's disease," <u>J. Pediatr. Gastroenterol. Nutr.</u> , 27:A8 (1998).
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<i>JLc</i>	HY	Rosenberg et al., "A controlled trial of azathioprine in the management of ulcerative colitis," <u>Gastroenterol.</u> , 69:96-99 (1975). (July, 1975).

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<i>JL</i>	HZ!	Van Os et al., "Azathioprine pharmacokinetics after intravenous, oral, delayed release oral and rectal foam administration," <u>Gut</u> , 39:63-68 (1996).
<i>JL</i>	IR!	Van Os et al., "Simultaneous determination of azathioprine and 6-mercaptopurine by high-performance liquid chromatography," <u>J. Chromatog. B</u> , 679:147-154 (1996).
<i>JL</i>	IS	Willoughby et al., "Controlled trial of azathioprine in Crohn's disease," <u>Lancet</u> , 731:944-947 (October 30, 1971).

! Month of publication data is unavailable for this reference.

EXAMINER L. E. Crane <i>L.E.Crane</i>	DATE CONSIDERED 04/14/00
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.